ERLEADA® (apalutamide) Prior Authorization Checklist ☑

Reminders and Tips When Completing Prior Authorization for Your Patients

Each health plan may have their own unique prior authorization (PA) form with varying requirements. It is important to gather necessary information during the patient's first appointment to ensure successful navigation of the process with minimal delays. This necessary information may include, but is not limited to:

- ❑ Patient demographics (date of birth, gender, phone, email, and address)
- ❑ Patient insurance information (copy front and back of patient's prescription [drug] and health [medical] card)
- ❑ Patient health charts and past medical history
  - – Including comorbidities and treatment history for prostate cancer (PSA, lab results, imaging, treatment plan)

Remember: Submit PA through a patient's pharmacy benefits

With the above completed, proceed to the following:

Current Patient information

- **Provide required:**
  - ❑ Patient demographics
  - ❑ Patient insurance information

Drug Information

- **Prescribed by:**
  - ❑ Oncologist and/or Urologist
- **Prescription Information:**
  - ❑ Dose [recommended dose of ERLEADA® is 240 mg (four 60 mg tablets) administered orally once daily*]
  - ❑ Quantity
  - ❑ Days supplied

Diagnosis and Clinical Information

Diagnosis

❑ **Metastatic castration-sensitive prostate cancer (mCSPC)**
- – ICD-10 code - C61* Malignant neoplasm of prostate
- – Proof of patient on androgen deprivation therapy (ADT)
- – Proof patient is metastatic (bone metastasis)

❑ **Non-metastatic castration-resistant prostate cancer (nmCRPC)**
- – ICD-10 code - C61* Malignant neoplasm of prostate
- – Proof of patient on ADT
- – Proof of PSA doubling time†

❑ ***NOTE: Use additional code to identify (if necessary):***
- – Hormone sensitivity status (Z19.2)
- – Rising PSA following treatment for malignant neoplasm of prostate (R97.21)

*For a full description of Prescribing Information, including appropriate doses, see indication, dosing, and administration information below, including Important Safety Information.
†Patients who enrolled in the SPARTAN study were required to have a PSA doubling time of ≤10 months. See ERLEADA® Prescribing Information for further information.
PSA = prostate-specific antigen.

Diagnosis and Clinical Information continued on next page

Please see page 4 for Important Safety Information and click here for full Prescribing Information.

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Diagnosis and Clinical Information (continued)

❑ **Patient history of therapy:**

- Date of onset of prostate cancer
- Must have one of the following:
  - ❑ Combination treatment with gonadotropin-releasing hormone (GnRH) analog;
    OR
  - ❑ Bilateral orchiectomy
- Must be on continuity of therapy
- Clinical Rationale for Requested Medication (Guidelines/Provider's Plan for Patient)

Documents to Support Clinical Information

❑ **Supporting Clinical information**

- Lab results and dates (PSA doubling time ❑ Yes ❑ No)
- Imaging reports
- Request for initiation of therapy or a continuation of therapy
- Other PA required supporting clinical information not listed

❑ **Patient medication history (including treatments from previous healthcare providers):**

- Medication and duration of previous prostate cancer therapy
- Clinical response
- Allergies
- Female partner of reproductive potential (❑ Yes ❑ No)
  - **IF YES –** is the patient's partner pregnant? (❑ Yes ❑ No)
  - **IF NO –** has the patient or will the patient be instructed to practice effective contraception during therapy and for 3 months after stopping ERLEADA® therapy (❑ Yes ❑ No)
- Strength
- Schedule
- Contraindications

Other Supporting Documentation Potentially Needed

❑ **Letter of Medical Necessity**

- Visit http://www.janssencarepath.com/hcp/erleada for a sample letter of medical necessity
- For an expedited request (not automatic), adequate information should be provided to support the urgent nature of the request

❑ **Patient Authorization and Notice of Release of Information**

❑ **Product Full Prescribing Information**

❑ **Patient History/Chart Notes**

❑ **Pertinent Clinical Studies (Spartan and Titan)**

Contact your **Janssen Field Reimbursement Access Specialist (FRAS)** or the patient's insurer if you have questions.

We can help make it simple for you to help your patients. Janssen CarePath is your one source for access, affordability, and treatment support for your patients. Janssen CarePath helps verify insurance coverage for your patients, provides reimbursement information, helps find financial assistance options for eligible patients, and provides ongoing support to help patients start and stay on prescribed Janssen medications.

Call a Janssen CarePath Care Coordinator at 877-CarePath (877-227-3728), Monday–Friday, 8:00 AM to 8:00 PM ET.

Sign Up or Log In to the Provider Portal at JanssenCarePathPortal.com.

Visit JanssenCarePath.com.

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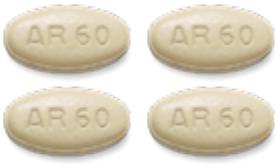
Erleada® (apalutamide) 60 mg tablets

ERLEADA® (apalutamide) Indications, Dosing, and Administration

ERLEADA® is indicated for the treatment of metastatic castration-sensitive prostate cancer (mCSPC) or for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC).



Tablets shown are actual size.

The recommended dose of ERLEADA® is 240 mg (four 60 mg tablets) administered **ORALLY ONCE DAILY**[1]

Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy.[1]

No need for co-administration of a corticosteroid.[1]

Can be taken with or without food. Tablets should be swallowed whole.[1]

No initial dose adjustments for ERLEADA® are necessary for renal or hepatic impairment.*[1]

*ERLEADA® has not been evaluated in patients with severe renal or hepatic impairment.

Dosage modification

- If Grade 3 or greater adverse reactions, or other intolerable adverse reactions occur, withhold ERLEADA®. Consider permanent discontinuation of ERLEADA® for Grade 3 or 4 cerebrovascular and ischemic cardiovascular events. Permanently discontinue ERLEADA® for confirmed severe cutaneous adverse reactions (SCARs) or for other Grade 4 skin reactions. For other adverse reactions, when symptoms improve to less than or equal to Grade 1 or original grade, resume ERLEADA® at the same dose or a reduced dose (180 mg or 120 mg), if warranted.[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Fractures — In a randomized study (SPARTAN) of patients with nmCRPC, fractures occurred in 12% of patients treated with ERLEADA® and in 7% of patients treated with placebo. In a randomized study (TITAN) of patients with mCSPC, fractures occurred in 9% of patients treated with ERLEADA® and in 6% of patients treated with placebo. Evaluate patients for fracture risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone-targeted agents.

Falls — In a randomized study (SPARTAN), falls occurred in 16% of patients treated with ERLEADA® compared with 9% of patients treated with placebo. Falls were not associated with loss of consciousness or seizure. Falls occurred in patients receiving ERLEADA® with increased frequency in the elderly. Evaluate patients for fall risk.

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Important Safety Information

WARNINGS AND PRECAUTIONS

Cerebrovascular and Ischemic Cardiovascular Events — In a randomized study (SPARTAN) of patients with nmCRPC, ischemic cardiovascular events occurred in 3.7% of patients treated with ERLEADA® and 2% of patients treated with placebo. In a randomized study (TITAN) in patients with mCSPC, ischemic cardiovascular events occurred in 4.4% of patients treated with ERLEADA® and 1.5% of patients treated with placebo. Across the SPARTAN and TITAN studies, 4 patients (0.3%) treated with ERLEADA® and 2 patients (0.2%) treated with placebo died from an ischemic cardiovascular event. Patients with history of unstable angina, myocardial infarction, congestive heart failure, stroke, or transient ischemic attack within 6 months of randomization were excluded from the SPARTAN and TITAN studies.

In the SPARTAN study, cerebrovascular events occurred in 2.5% of patients treated with ERLEADA® and 1% of patients treated with placebo. In the TITAN study, cerebrovascular events occurred in 1.9% of patients treated with ERLEADA® and 2.1% of patients treated with placebo. Across the SPARTAN and TITAN studies, 3 patients (0.2%) treated with ERLEADA®, and 2 patients (0.2%) treated with placebo died from a cerebrovascular event. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Consider discontinuation of ERLEADA® for Grade 3 and 4 events.

Cerebrovascular and ischemic cardiovascular events, including events leading to death, occurred in patients receiving ERLEADA®. Monitor for signs and symptoms of ischemic heart disease and cerebrovascular disorders. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Consider discontinuation of ERLEADA® for Grade 3 and 4 events.

Fractures — In a randomized study (SPARTAN) of patients with nmCRPC, fractures occurred in 12% of patients treated with ERLEADA® and in 7% of patients treated with placebo. In a randomized study (TITAN) of patients with mCSPC, fractures occurred in 9% of patients treated with ERLEADA® and in 6% of patients treated with placebo. Evaluate patients for fracture risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone-targeted agents.

Falls — In a randomized study (SPARTAN), falls occurred in 16% of patients treated with ERLEADA® compared with 9% of patients treated with placebo. Falls were not associated with loss of consciousness or seizure. Falls occurred in patients receiving ERLEADA® with increased frequency in the elderly. Evaluate patients for fall risk.

Seizure — In two randomized studies (SPARTAN and TITAN), 5 patients (0.4%) treated with ERLEADA® and 1 patient treated with placebo (0.1%) experienced a seizure. Permanently discontinue ERLEADA® in patients who develop a seizure during treatment. It is unknown whether anti-epileptic medications will prevent seizures with ERLEADA®. Advise patients of the risk of developing a seizure while receiving ERLEADA® and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others.

Severe Cutaneous Adverse Reactions — Fatal and life-threatening cases of severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) occurred in patients receiving ERLEADA®.

Monitor patients for the development of SCARs. Advise patients of the signs and symptoms of SCARs (eg, a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy). If a SCAR is suspected, interrupt ERLEADA® until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, or for other Grade 4 skin reactions, permanently discontinue ERLEADA® *[see Dosage and Administration (2.2)]*.

Embryo-Fetal Toxicity — The safety and efficacy of ERLEADA® have not been established in females. Based on findings from animals and its mechanism of action, ERLEADA® can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of ERLEADA® *[see Use in Specific Populations (8.1, 8.3)]*.

ADVERSE REACTIONS

The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥2% over placebo) from the randomized placebo-controlled clinical trials (TITAN and SPARTAN) were fatigue, arthralgia, rash, decreased appetite, fall, weight decreased, hypertension, hot flush, diarrhea, and fracture.

Laboratory Abnormalities — All Grades (Grade 3-4)

- **Hematology —** In the TITAN study: white blood cell decreased ERLEADA® 27% (0.4%), placebo 19% (0.6%). In the SPARTAN study: anemia ERLEADA® 70% (0.4%), placebo 64% (0.5%); leukopenia ERLEADA® 47% (0.3%), placebo 29% (0%); lymphopenia ERLEADA® 41% (1.8%), placebo 21% (1.6%)
- **Chemistry —** In the TITAN study: hypertriglyceridemia ERLEADA® 17% (2.5%), placebo 12% (2.3%). In the SPARTAN study: hypercholesterolemia ERLEADA® 76% (0.1%), placebo 46% (0%); hyperglycemia ERLEADA® 70% (2%), placebo 59% (1.0%); hypertriglyceridemia ERLEADA® 67% (1.6%), placebo 49% (0.8%); hyperkalemia ERLEADA® 32% (1.9%), placebo 22% (0.5%)

Rash — In 2 randomized studies (SPARTAN and TITAN), rash was most commonly described as macular or maculopapular. Adverse reactions of rash were 26% with ERLEADA® vs 8% with placebo. Grade 3 rashes (defined as covering >30% body surface area [BSA]) were reported with ERLEADA® treatment (6%) vs placebo (0.5%).

The onset of rash occurred at a median of 83 days. Rash resolved in 78% of patients within a median of 78 days from onset of rash. Rash was commonly managed with oral antihistamines, topical corticosteroids, and 19% of patients received systemic corticosteroids. Dose reduction or dose interruption occurred in 14% and 28% of patients, respectively. Of the patients who had dose interruption, 59% experienced recurrence of rash upon reintroduction of ERLEADA®.

Hypothyroidism — In 2 randomized studies (SPARTAN and TITAN), hypothyroidism was reported for 8% of patients treated with ERLEADA® and 1.5% of patients treated with placebo based on assessments of thyroid- stimulating hormone (TSH) every 4 months. Elevated TSH occurred in 25% of patients treated with ERLEADA® and 7% of patients treated with placebo. The median onset was at the first scheduled assessment. There were no Grade 3 or 4 adverse reactions. Thyroid replacement therapy, when clinically indicated, should be initiated or dose adjusted.

DRUG INTERACTIONS

Effect of Other Drugs on ERLEADA® — Co-administration of a strong CYP2C8 or CYP3A4 inhibitor is predicted to increase the steady-state exposure of the active moieties. No initial dose adjustment is necessary; however, reduce the ERLEADA® dose based on tolerability *[see Dosage and Administration (2.2)]*.

Effect of ERLEADA® on Other Drugs

CYP3A4, CYP2C9, CYP2C19, and UGT Substrates — ERLEADA® is a strong inducer of CYP3A4 and CYP2C19, and a weak inducer of CYP2C9 in humans. Concomitant use of ERLEADA® with medications that are primarily metabolized by CYP3A4, CYP2C19, or CYP2C9 can result in lower exposure to these medications. Substitution for these medications is recommended when possible or evaluate for loss of activity if medication is continued. Concomitant administration of ERLEADA® with medications that are substrates of UDP-glucuronosyl transferase (UGT) can result in decreased exposure. Use caution if substrates of UGT must be co-administered with ERLEADA® and evaluate for loss of activity.

P- gp, BCRP, or OATP1B1 Substrates — Apalutamide is a weak inducer of P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), and organic anion transporting polypeptide 1B1 (OATP1B1) clinically. Concomitant use of ERLEADA® with medications that are substrates of P-gp, BCRP, or OATP1B1 can result in lower exposure of these medications. Use caution if substrates of P-gp, BCRP, or OATP1B1 must be co-administered with ERLEADA® and evaluate for loss of activity if medication is continued.

cp-50507v6

Please see the full Prescribing Information for ERLEADA®.

References: 1. ERLEADA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** American Medical Association. ICD-10-CM 2018; The Complete Official Code Book. Chicago, IL: Optum 360 LLC; 2017.

Erleada® (apalutamide) 60 mg tablets